IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Lex P. Jansen et al.	Art Unit	: 3731
Serial No.	: 10/063,125	Examiner	: Ryan J. Severson
Filed	: March 22, 2002	Conf. No.	: 5949
Title	: MRI AND X-RAY COMPATIBLE STENT MATERIAL		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

A Notice of Appeal from the rejection of the pending application (U.S. Application No. 10/063,125) was filed on January 15, 2009.

(1) Real Party in Interest

The real party in interest is Boston Scientific Scimed, Inc. (formerly SciMed Life Systems, Inc.)

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 1, 3, 6-8, 26-28, and 32-38 are pending and stand finally rejected. Claims 2, 4, 5, 9-25, 29-31 are canceled. Appellants are appealing herein the rejection of claims 1, 3, 6-8, and 32-35 under 35 U.S.C. § 103(a) as being unpatentable over Gianturco, U.S. Patent No. 4,800,882 ("Gianturco") in view of Mayer, U.S. Patent No. 5,630,840 ("Mayer"), and the rejection of claims 26-28 and 36-38 under 35 U.S.C. § 103(a) over Gianturco in view of Mayer and Campbell, U.S. Patent No. 5,632,840 ("Campbell").

(4) Status of Amendments

All amendments have been entered.

(5) Summary of Claimed Subject Matter

The claims feature stents incorporating alloys having specific percentage ranges of tungsten and rhenium. Claims 1 and 32 are independent in form. Each independent claim requires an expandable medical implant for implantation in a bodily vessel, the implant:

- having a flow passage therethrough (*see e.g.,* specification, page 4, paragraph 20),
- being in the form of a stent comprising a body having a generally tubular shape (*see e.g.,* specification, page 5, paragraph 28),
- having a body capable of maintaining patency in a blood vessel (*see e.g.*, specification, page 8, paragraph 42),
- having a body consisting essentially of an alloy comprising tungsten and rhenium (*see e.g.,* specification, page 5, paragraph 29).

Claim 1 (as well as dependent claims 3, 6-8, and 26-28) specify that in the alloy comprising tungsten and rhenium, tungsten is present in an amount ranging from about 75 weight percent to about 99 weight percent (*see e.g.*, specification, pages 5-6, paragraph 29). Claim 32 (and dependent claims 33-38) specify that in the alloy comprising tungsten and rhenium, rhenium is present in an amount ranging from about 1 weight percent to about 25 weight percent (*see e.g.*, specification, page 6, paragraph 29).

A stent including a body consisting essentially of the claimed tungsten-rhenium enhances the stent's radiopacity without interfering with MRI compatibility or impairing other important stent properties, such as the elasticity of the material. Stents are medical implants involving complex structures having a variety of mechanical and material properties unique to the performance of stents during and after deployment. Stents are typically made from strands of material formed into a tube, of rolled sheets of material with openings, or of tubes with material removed therefrom to form a stent pattern. Stents are desirably expandable to open the body lumen at the point of deployment and to maintain the patency of the body vessel. Stents may be balloon expandable, self-expanding, or a combination of self expanding and balloon expandable. Because stents are delivered through often-tortuous vessels, they must also be flexible. In order to achieve a desirable flexibility and expandability, the stent material should also have a high modulus of elasticity. At the same time, the stent material should be sufficiently radiopaque to be visible under fluoroscopy. And with widespread use of Magnetic Resonance Imaging (MRI),

it is desirable for the stent material to be MRI compatible so as not to distort any magnetic resonance images that may be taken of the body in the region of the stent. The claimed alloys, with the specified weight percentages of tungsten and rhenium, have extremely useful properties when used as the body of a stent, including a high modulus of elasticity for desired flexibility and expansion, as well as improved radiopacity and MRI compatibility. Accordingly, the use a body consisting essentially of claimed tungsten-rhenium alloys provides an important solution to the need for a flexible, expandable stent with suitable radiopacity and MRI compatibility not found in the prior art.

(6) Grounds of Rejection to be Reviewed on Appeal

Claims 1, 3, 6-8, and 32-35 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Gianturco, U.S. Patent No. 4,800,882 ("Gianturco") in view of Mayer, U.S. Patent No. 5,630,840 ("Mayer"). Claims 26-28 and 36-38 stand finally rejected under 35 U.S.C. § 103(a) over Gianturco in view of Mayer and Campbell, U.S. Patent No. 5,632,840 ("Campbell"). Appellants are appealing these rejections herein.

(7) Argument

A. Claims 1, 3, 6-8, and 32-35 are Patentable over Gianturco in view of Mayer

The rejection of claims 1, 3, 6-8, and 32-35 under 35 U.S.C. 103(a) over Gianturco in view of Mayer is in error because a person having ordinary skill in the art at the time of invention would not find it obvious to make a stent having a "body consisting essentially of an alloy comprising tungsten and rhenium," as claimed based on the disclosures of Gianturco and/or Mayer.

Gianturco discloses a wire stent that "is made of a malleable material, preferably from the group comprising annealed stainless steel, tungsten and platinum." Gianturco, col. 3, lines 63-65. Gianturco does not disclose or suggest the use of a wire that "consists essentially of an alloy comprising tungsten and rhenium." Gianturco goes on to discuss the properties of the malleable material in the following passage:

> This malleable material is sufficiently deformable to allow the loops 15 and 16 to diverge due to radially outward pressure applied by inflation of the membrane that

> comprises the standard balloon catheter. Because the stent material is plastic, rather than elastic, the stent retains the enlarged diameter after the balloon 23 is deflated and the catheter 22 removed. However, the material has sufficient strength and stiffness to avoid the stent being displaced on the balloon during insertion and to avoid the loops 15 and 16 being forced into an overlying relation. Further, the stent has sufficient strength and stiffness to allow it to maintain its position in the passageway and to resist being dislodged after the catheter 22 has been removed and the balloon is no longer stabilizing the stent.

Gianturco, col. 3, line 65 – col. 4 line 11.

The Office Action asserts that it would have been obvious to replace the tungsten material disclosed by Gianturco with the tungsten-rhenium alloy disclosed by Mayer. This rejection, however, ignores the structural difference between Gianturco and Mayer. Gianturco discloses a wire, while Mayer discloses a composite filament having a core and a casing. Nothing in Mayer would suggest to a person having ordinary skill in the art that she should substitute Mayer's core, without the casing, for Gianturco's wire. The Examiner is taking Mayer out of context, picking and choosing parts of Mayer's structure, while ignoring the portions of the Mayer disclosure that undermine the Examiner's conclusory assertion of obviousness.

Mayer discloses a composite filament such as that shown in Figs. 4, 11, 13, and 14 (reproduced below). Each filament includes at least a core (e.g., 24, 76, 82, or 90) and a casing (e.g., 26, 78, 84, or 92). The combination of the core and the casing provides a filament structure that provides the stent with suitable flexibility and radiopacity. Mayer does not disclose or even suggest the use of the core without the presence of the cladding. Mayer states that the core "conforms to the shape of the case" and that "the mechanical behavior of the composite filament 18a in terms of elastic deformation in response to external stresses is, essentially, the behavior of the case 26." Mayer, col. 6, lines 14-21. Accordingly, one having ordinary skill in the art would not find it obvious to substitute the core material of Mayer alone for Gianturco's wire.

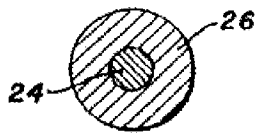

FIG. 4

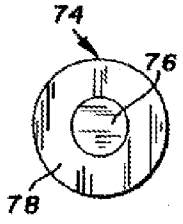

FIG. 11

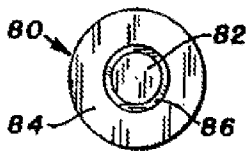

FIG. 13

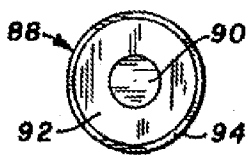

FIG. 14

Mayer discloses one embodiment of a core including "a tungsten-based alloy including rhenium at 5-40 weight percent." Mayer, col. 11, lines 55-58. Mayer does not suggest that this alloy would have the properties suitable for Gianturco's wire. In particular, there is no indication that the tungsten-based alloy disclosed by Mayer would be "plastic, rather than elastic," yet have "sufficient strength and stiffness to avoid the stent being displaced on the balloon during insertion and to avoid the loops 15 and 16 being forced into an overlying relation" and also have "sufficient strength and stiffness to allow it to maintain its position in the passageway and to resist being dislodged after the catheter 22 has been removed and the balloon is no longer stabilizing the stent." While Mayer only indicates the disclosed alloy could be used in composite filament in combination with a cladding, it was the Appellants that discovered that the claimed alloy has properties suitable for use as a stent body. Because there is no indication in either Gianturco or Mayer that the claimed alloy alone would have the properties suitable for a stent body, the rejection is improper and should be reversed.

There is also no support for the Examiner's position that one having ordinary skill in the art would use the core material of Mayer, without the casing material of Mayer, to make the stent of Gianturco "to provide a stent with sufficient flexibility and radiopacity." This reason is a legally deficient alleged "reason" for the combination of Gianturco and Mayer because there is no disclosure or suggestion in either Mayer nor Gianturco that the core material of Mayer would have "sufficient flexibility" for use as a stent. Furthermore, as discussed above, there is also no suggestion that the core material of Mayer would have the other properties disclosed by Gianturco. Because the reasons asserted by the Examiner for the alleged combination are deficient, the rejection is in error and must be reversed.

The Examiner is also misapplying the law regarding the obviousness of "select[ing] a known material on the basis of its suitability for the intended use" and the ruling in *In re Leshin*, 277 F.2d 197, 125 USPQ 416 (CCPA 1960). The core material of Mayer was only known as being a core material used in combination with one or more of the casing materials of Mayer. The Examiner has not presented any evidence that the core material of Mayer was known as being a material that could be used alone as the body of a stent. That was the Appellants' discovery. Because the Examiner has not presented any evidence that a person having oridinary

skill in the art would recognize the core material of Mayer as being useful for anything other than a core material used in combination with a casing material, as disclosed by Mayer, the Examiner's reliance on the ruling in *In re Leshin* is misplaced. "Where the legal conclusion [of obviousness] is not supported by facts it cannot stand." *In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967).

Appellants also note that the claims exclude the structure of a case and core, disclosed by Mayer. *See* Office Action, page 4, lines 1-5. Both independent claims 1 and 32 recite "a body having a generally tubular shape," and "the body consisting essentially of an alloy comprising tungsten and rhenium." The Mayer device does not have a body having a generally tubular shape that consists essentially of an alloy comprising tungsten and rhenium, as claimed. The core *alone* of Mayer is not woven into a generally tubular shape. Appellants have already overcome the rejection of the claims over Mayer based on the Examiner's improper claim construction and object to the Examiner's attempt to again raise this issue without actually making the rejection. *See* Response filed April 10, 2008.

B. Claims 26-28 and 36-38 are Patentable over Gianturco in view of Mayer and Campbell

The rejection of claims 26-28 and 36-38 over Gianturco in view of Mayer and Campbell is also improper for the reasons given above. Campbell also does not disclose or suggest that the core alloy disclosed by Mayer has the properties suitable for Gianturco's wire. Accordingly, this rejection is also improper and should also be reversed.

The brief fee of $540 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 3/3/2009

/Geoffrey P. Shipsides, Reg. No. 55,617/
Geoffrey P. Shipsides
Reg. No. 55,617

Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, Minnesota 55402
Telephone: (612) 335-5070
Facsimile: (877) 769-7945

Appendix of Claims

1. An expandable medical implant for implantation in a bodily vessel, the implant having a flow passage therethrough, the implant being in the form of a stent comprising a body having a generally tubular shape, the body capable of maintaining patency in a blood vessel, the body consisting essentially of an alloy comprising tungsten and rhenium, wherein the tungsten is present in an amount ranging from about 75 weight percent to about 99 weight percent.

3. The medical implant of claim 1 wherein the alloy consists essentially of tungsten and rhenium.

6. The medical implant of claim 1 wherein the rhenium is present in an amount ranging from about 25 weight percent to about 1 weight percent.

7. The medical implant of claim 1 wherein the modulus of elasticity is at least 400 GPa.

8. The medical implant of claim 1 having a sidewall and a plurality of openings therein, the implant formed from a sheet or from a tube, the openings having been formed by removing material from the sheet or tube.

26. The medical implant of claim 1 further comprising a drug or a therapeutic agent on the body.

27. The medical implant of claim 1 further comprising a coating on the body.

28. The medical implant of claim 27 wherein the coating comprises a polymer.

32. An expandable medical implant for implantation in a bodily vessel, the implant having a flow passage therethrough, the implant being in the form of a stent comprising a body having a generally tubular shape, the body capable of maintaining patency in a blood vessel, the body consisting essentially of an alloy comprising tungsten and rhenium, wherein the rhenium is present in an amount ranging from about 1 weight percent to about 25 weight percent.

33. The medical implant of claim 32, wherein the alloy consists essentially of tungsten and rhenium.

34. The medical implant of claim 32, wherein the modulus of elasticity is at least 400 GPa.

35. The medical implant of claim 32, having a sidewall and a plurality of openings therein, the implant formed from a sheet or from a tube, the openings having been formed by removing material from the sheet or tube.

36. The medical implant of claim 32, further comprising a drug or a therapeutic agent on the body.

37. The medical implant of claim 32, further comprising a coating on the body.

38. The medical implant of claim 37, wherein the coating comprises a polymer.

Evidence Appendix

None.

Related Proceedings Appendix

None.